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Installation and Operation Manual

M9 UltraClave™ Steam Sterilizer

(For M9's with Protective Drying Retrofit Kit)

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Owner's Product Identification

(information that you'll need to provide for servicing - key information is highlighted)

The serial number for the sterilizer is located on the back panel of the unit next to the power supply receptacle. Please record the unit's serial number and date of purchase below:

Date of Purchase

Serial Number

Name of Owner/Facility/Department

Name of Authorized Midmark Dealer

Telephone # of Authorized Midmark Dealer

Address of Authorized Midmark Dealer

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Safety First

The primary concern of Midmark Corporation is that this equipment be operated and maintained with the safety of the patient and doctor in mind. To assure safer and more reliable operation (1) Read this manual before installing or operating your equipment; (2) Assure that appropriate personnel are informed of the contents of this manual and that the manual remains accessible for future reference; (3) Understand the instructions contained in this manual before attempting to install or operate this equipment.

Recommended Steam Sterilization Monitoring Program

All functions of the sterilizer should be monitored to provide maximum sterility assurance. We recommend using our printer to provide a permanent record of actual exposure times and temperatures.

For additional assurance that minimum sterilizing conditions have been achieved, we recommend the use of a quality chemical indicator with each cycle and within each package.

Since chemical indicators do not prove sterilization, biological monitoring is considered the reliable method for verifying the sterilization process. According to the CDC (Centers for Disease Control) whose guidelines are now enforced by OSHA, "All sterilizers should be (biologically) monitored at least once a week using commercial preparations of spores intended specifically for that type of sterilizer (i.e., Bacillus stearothermophilus for steam sterilizers and Bacillus subtillis for ethylene oxide and dry heat sterilizers)."

Explanation of Safety Symbols

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is limited to the most extreme situations.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

EQUIPMENT ALERT

Indicates an imminently or potentially hazardous situation which, if not avoided, will or may result in serious, moderate, or minor equipment damage.

NOTE

Note is used to amplify an operating procedure, practice, or condition.

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Specifications - M9

PHYSICAL DIMENSIONS

Overall Length ..... 19" (483 mm)
Overall Width ..... 15" (381 mm)
Overall Height ..... 16" (406 mm)
Counter Area ..... 16 1/2" x 14"
(419 mm x 356 mm)
Chamber ..... 9" Dia x 15"
(229 mm Dia x 381 mm)

Trays
(Large) (2) ..... 12" x 8" x 1"
(305 mm x 203 mm x 25 mm)

(Small) (2) ..... 12" x 5 1/2" x 1"
(305 mm x 140 mm x 25 mm)

WEIGHT
Empty ..... 73 Lb (33 Kg)
With Shipping Carton ..... 81 Lb (37 Kg)

WATER RESERVOIR CAPACITY APPROX. ..... 0.88 GAL.
(3.31 Liters to Full Mark)

ELECTRICAL REQUIREMENTS
220-240 VAC, 50-60 Hz Model ..... 10 AMP Circuit, Single Phase

A separate (dedicated) circuit is recommended for this sterilizer. The sterilizer should not be connected into an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load.

MAXIMUM POWER CONSUMPTION
220-240 VAC, 50-60 Hz Model ..... 1500 Watts, 6.3 A @ 240 V

Chamber Pressure At 270°F (132°C) ..... 31 PSI (215 kPa)

Safety Valve Setting ..... 35 PSI (241 kPa)

Safety Features

The design of the M9 UltraClave™ incorporates several safety features for your protection.

Door Stop
The door stop prevents the door from opening fully if there is a slight residual pressure in the chamber when the door handle is operated.

Door Closed Switch
The door closed switch is used to signal the autoclave that the door is completely closed. This switch is activated just as the door becomes fully closed. An audible signal will sound and the “Door Ajar” light will flash if the door is not fully closed.

Water Low Indicator
The water low indicator signals the operator if there is insufficient water to fill the chamber to the proper level. An audible signal will sound and the “Water Low” light will flash if the reservoir needs to be refilled with water.

Overheat Protection
Chamber temperature is monitored. If chamber temperature reaches or exceeds 295°F (146°C), power to the sterilizer is cut off.

Pressure Relief Valve
The pressure relief valve opens to provide backup protection to reduce chamber pressure in the event that the chamber steam pressure exceeds 35 PSI (241 kPa). Released steam is directed out of the bottom of the cabinet. An access cover is located on the top cover for relief valve operational checks.

Fault Detection Circuit
All functions of the sterilizer are monitored during a cycle. If a fault occurs during the cycle, the autoclave monitoring circuitry will stop the cycle, sound an audible signal, and light a flashing “error” lamp.

Installation

LOCATION OF STERILIZER

DANGER

Do not operate this sterilizer in areas where flammable anesthetics are used or stored. An explosion could occur causing possible bodily injury.

Adherence to the following recommendations for location of the sterilizer will contribute to optimum operation of the unit. (Refer to Figure 1 to identify locations specified in the text.)

Support Surface (A) — Sterilizer must be placed on a Level Surface to ensure that the chamber will fill correctly. Improper water level in the chamber could cause a sterilizer malfunction.

Support Surface Material (B) — Formica, stainless steel or other water and heat resistant material. Heat from bottom of sterilizer could reach 160°F (71°C) on the support surfaces for short periods of time.

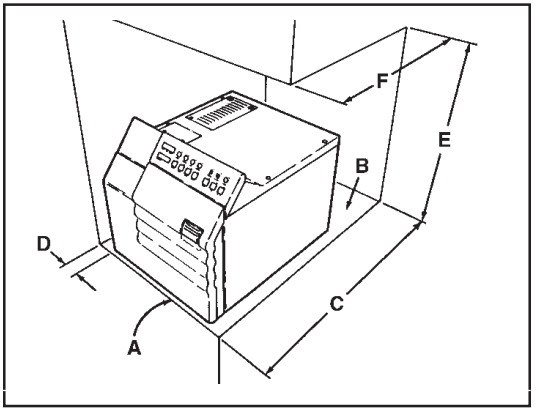


Figure 1

Support Surface Depth (C) — Support surface should be approximately 18" (460 mm) deep for the M9. Allow at least 2" (51 mm) clearance behind the sterilizer for air circulation.

Distance To Side Wall (D) — If the sterilizer is located next to side walls, there should be no less than 2" (51 mm) clearance between the side of the sterilizer and the wall.

Distance Above Sterilizer (E) — If the sterilizer is to be located beneath wall cabinets or shelves, the underside of the cabinets or shelves should be at least 22" (559 mm) above the support surface for the M9 to provide access to the top inspection cover and to allow for changing the printer paper roll.

Overhang (F) — If the sterilizer is to be located beneath an overhang the underside of the overhang should project no further than 15" (381 mm) over the rear of the sterilizer.

Location On Support Surface — The front of the sterilizer should be located near the front of the support surface so water can be easily drained from the drain tube into a container.

Neighboring Materials & Equipment — If the sterilizer will be operated in continuous cycles, locate the sterilizer where excessive emission of steam will not damage materials or equipment in the surrounding area.

RELOCATION OF STERILIZER

- Be sure power cord is disconnected from the electrical outlet.
- Be sure sterilizer is cool enough for handling.
- Drain water from reservoir or take care not to tip the sterilizer, spilling water from the reservoir.

General Description

DESCRIPTION OF STERILIZER

The M9 UltraClave™ Sterilizers have been designed for use in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities where a variety of materials require processing.

The UltraClave™ Sterilizers can be used to sterilize numerous items as follows: Wrapped or unwrapped instruments, pouches of instruments, linen packs, liquids, ampoules, brushes, dressings, glassware, needles, rubber gloves, rubber catheters, rubber sheeting, treatment trays, solutions, sutures, syringes, tubing, utensils.

Check with your supply manufacturer for specific sterilization instructions. All supplies requiring a common exposure period may be safely and economically sterilized in the same load with the exception of rubber gloves, liquids, and solutions.

An optional printer may be used on all UltraClave™ models to provide a permanent record of actual exposure temperatures and exposure times.

DANGER

Do not use this sterilizer for sterilizing volatile substances and materials that would cause toxic or explosive conditions which would result in serious injury or death.

Operational Features

- The sterilizer will begin a sterilization program cycle when a sterilization program is selected, the door is closed and fully latched, and the “Start” switch is pressed.
- The sterilizer will automatically fill the chamber with water to the correct level once the “Start” switch is pressed.
- The cycle time countdown will begin only after the proper pressure and temperature have been reached.
- When the sterilization phase is complete, steam pressure is automatically exhausted from the chamber and an automatic closed door drying phase is initiated.
- An automatic drying phase will run for 45 minutes, but goods that do not require drying may be removed at any time after the sterilization phase has been completed.
- When the drying phase is complete, five audible “beeps” signal the operator that the sterilization program cycle is now complete. The sterilizer may be turned to standby at this time, or restarted if additional sterilization programs are desired.

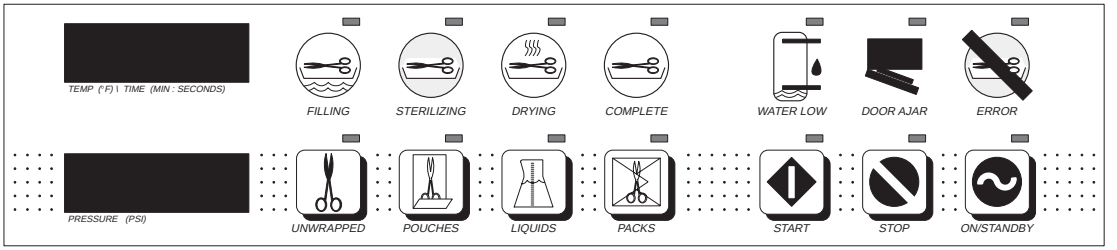


Figure 2

MA207703

Indicators and Controls

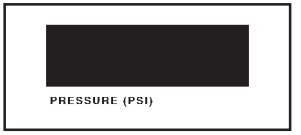
The display panel in Figure 2 shows the location of the following indicators and controls.

INDICATORS:

The following is a description of the indicators and their function:

1. Temperature/ Time Display:
When a cycle is selected, the Temperature/ Time Display alternately indicates cycle temperature and exposure time. During a cycle, the cycle time remaining is displayed.

2. Pressure Display:
The Pressure Display indicates chamber pressure during the cycle.



3. Filling Indicator:
The Filling indicator light illuminates when the chamber is being filled with water.

4. Sterilizing Indicator:
The Sterilizing indicator light illuminates during the heat up and sterilization phases of the program.

5. Drying Indicator
The Drying indicator light illuminates during the drying phase of the program.

6. Complete Indicator:
The Complete indicator light illuminates when the sterilizer has completed the program.

The sterilized goods may be removed once this is lit.

7. Water Low Indicator:
The Water Low indicator light flashes and a beep sounds when the water level is too low in the reservoir to initiate a cycle.

8. Door Ajar Indicator:
The Door Ajar indicator light flashes and a beep sounds when the door is not completely latched.

9. Error Indicator:
The Error indicator light flashes and a beep sounds if a program was terminated before completion.

NOTE

A corresponding error code is displayed on the Temperature/Time display any time an error occurs. See the Error Code Guide (Table 3) for detailed explanations of error codes.

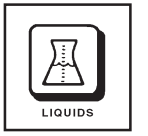
Controls

The UltraClave Sterilizer has four available sterilization program cycles to choose from as follows:

1. Unwrapped:
Depress the “Unwrapped” padswitch to select a program cycle designed to process unwrapped instruments at (270°F) 132°C for 5 minutes with a 45 minute drying cycle following the sterilization phase.

2. Pouches:
Depress the “Pouches” padswitch to select a program cycle designed to process instruments in peel pouches or wrapped instruments at (270°F) 132°C for 15 minutes with a 45 minute drying cycle following the sterilization phase.

3. Liquids:
Depress the “Liquids" padswitch to select a program cycle designed to process nonvolatile liquids at (250°F) 121°C for 30 minutes.



4. Packs:
Depress the “Packs” padswitch to select a program cycle designed to process packs of instruments at (250°F) 121°C for 30 minutes with a 45 minute drying cycle following the sterilization phase.

NOTE

After pressing any of the four program switches, the Time/Temperature settings will be displayed. A 45 minute drying phase follows the unwrapped, pouches, and packs cycles.

5. Start:
Depress the “Start” padswitch to initiate a program cycle once a program cycle has been selected.

6. Stop:
Depress the “Stop” padswitch any time during a program cycle to terminate a program cycle.

7. On/Standby:
Depress the “On/Standby” padswitch to turn the sterilizer on and to standby mode or to abort a program cycle once it has been initiated. Standby mode shuts down all program switches and lights to prevent accidental program initiation.

PRINTER
The optional printer can be used on all UltraClave models. It provides a permanent record of the time, temperature, and pressure reached during a cycle. Refer to printer section in this manual for detailed information on printer features and operation.

DOOR HANDLE
The Door Handle slides up to unlatch and down to latch the door.

LEVEL INDICATOR/
RESERVOIR DRAIN TUBE
The Level Indicator/Reservoir Drain Tube indicates the water level in the reservoir and allows the reservoir to be drained quickly and easily. The tube is located to the left of the chamber opening on the front of the sterilizer and can be unsnapped from the front to permit drainage into a container.

EQUIPMENT ALERT

Failure to properly secure the drain tube to the retaining clips may result in damage to the clips or the door gasket.

FILL OPENING
The Fill Opening allows distilled or demineralized water to be poured into the reservoir from the front of the unit while the door is in the open position.

TRAYS AND TRAY RACK
A Tray Rack is provided for the inside of the sterilizer chamber to hold the instrument trays. The Tray Rack slides out of the chamber for periodic cleaning of the chamber, tray plate, tray rack, and the sterilizer filter. Two large and two small trays can be placed into the rack.

POWER SUPPLY CORD
A removable Power Supply Cord is provided for the UltraClave Sterilizer. The plug must be connected to a grounded receptacle that furnishes proper power, (see electrical requirements).

Operating Instructions

PREPARATION BEFORE OPERATION

1. Install sterilizer according to installation procedures described in this manual.
2. Check the serial number label on the back panel of the sterilizer for the voltage required and connect the electrical supply cord to a properly grounded outlet.

WARNING

USE ONLY DISTILLED OR DEMINERALIZED WATER. Normal tap water contains minerals, especially chlorides, which have corrosive effects on stainless steel. Failure to use distilled or demineralized water may cause serious deterioration and premature failure of the stainless steel chamber which could result in serious injury or death.

3. Open the door and pour distilled or demineralized water into the fill opening until the water level found in the Level Indicator/Reservoir Drain Tube is at the Top of the red/green label. (See Figure 3).
4. Make sure printer (optional) is turned on.

DANGER

Do not use this sterilizer for sterilizing volatile substances and materials that would cause toxic or explosive conditions which would result in serious injury or death.

5. As with any steam sterilizer, always use sterility maintaining wraps or packages. If instruments are not wrapped, sterility is compromised once the chamber is opened.

Cleaning Instruments

WARNING

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in unsterile instruments which could lead to personal injury or death.

EQUIPMENT ALERT

Processing goods using an incorrect sterilization program could result in unsterile goods and may damage instruments. Consult with your supply manufacturer for specific sterilization instructions.

1. Clean instruments only with clean hands and/or while wearing clean surgical gloves.
2. Thoroughly wash instruments to remove gross debris (either mechanically or using an ultrasonic cleaner).
3. Rinse instruments thoroughly.
4. Dry instruments if water has high chlorine or mineral level.

LOADING TRAYS

1. Joined instruments must be sterilized in an open position.
2. Place all containers so that they will drain.
3. When using sterilization pouches, set the pouches on their sides to maximize steam circulation and to facilitate drying.
4. Do not wrap instruments too tightly.

Inadequate sterilization may result from improper wrapping.

5. Do not stack trays on one another. At least one inch should separate trays.
6. Do not pack sterilizer chamber excessively or overload trays. Provide adequate space between instruments and packs for proper steam circulation and drying. Overloading may cause a sterilization failure.
7. Do not plug syringes or needles.
8. Disassemble syringes if possible.
9. Place a paper tray cover or linen towel in the bottom of the trays prior to placing instruments in them.
10. Vented liquid containers should not be filled to more than 75% of their capacity, to allow for fluid expansion and to prevent overflow. Depending on the user's desired results, many different container styles may be acceptable. Careful consideration of the liquid to be sterilized should guide the user in selection and use of appropriate containers and closures.

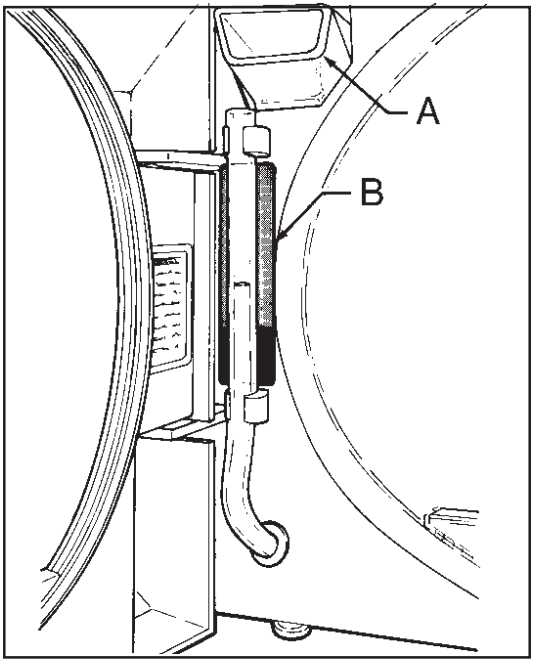


Figure 3: (A) Fill Spout; (B) Water Level Indicator

MONITOR LOADS

1. Include an internal process indicator strip with each sterilizer load to verify gross heat penetration.
2. A biological spore test indicator should be used weekly in a representative sterilizer load for sterilization assurance.

NOTE

Make sure the biological indicator spore test is manufactured specifically for use in a gravity type steam sterilizer. It is essential that all of the manufacturer's instructions for the biological indicators are followed exactly to insure representative results. It is especially important to adhere to cycle times and temperatures and placement of the biological indicator inside the sterilizer.

3. Sterilization indicators/monitors should be placed in the front bottom area of the sterilizer, or the most difficult location to sterilize.
4. For wrapped or packed instruments, place a sterilization indicator/monitor inside with the instruments.

NOTE

Check your local, state or national health care regulations and guidelines regarding the frequency of testing.

BASIC OPERATING STEPS

Four basic steps are required to start a sterilization program cycle after the load has been placed into the chamber and the door has been closed and latched.

(1) Press the “On/Standby” padswitch.

(2) Refer to Table 1 to select the proper sterilization program time and temperature.

(3) Select and press a sterilization program padswitch.

(4) Press the “Start” padswitch.

NOTE

Use sterility monitors with each load.

The drying phase of a sterilization program cycle cannot be initiated from the sterilizer control panel by itself. If the drying phase is desired, the operator must choose a program cycle that contains the drying phase, i.e. Unwrapped, Pouches, or Packs. The drying phase is automatically programmed when the operator chooses a program cycle that contains the drying phase; the only program cycle that does not contain the drying phase is the Liquids program cycle.

NOTE

Program selections can not be changed once the “Start” padswitch has been pressed. To change a program selection after a program cycle has been initiated, the program must be aborted (press the “Stop” or “On/Standby” padswitch and wait until the sterilizer has completed its shutdown safely). At that time a new program cycle may be initiated by following the steps above.

SHUTDOWN

The sterilizer will go into an automatic shutdown sequence if the “Stop” or “On/Standby” padswitch is pressed any time during a program cycle, with the exception of the drying phase. The shutdown sequence vents the chamber until the pressure reaches zero and the door can be opened.

If a power failure occurs during a cycle, the shutdown sequence will not activate and pressure may still exist in the chamber.

WARNING

Do not force door handle at any time. Chamber pressure may cause door to open with extreme force. If door handle does not move freely, allow unit to cool and depressurize 40 minutes before opening door. Personal injury may result.

Table 1. Suggested Times and Temperatures

PROGRAM	*TEMP/PRESS/TIME	ITEMS TO BE STERILIZED
UNWRAPPED	270°F (132°C)/27 PSI (186 kPa) for 5 Minutes	Nonsurgical instruments loose on a tray. Open glass or metal canisters. Heat resistant rubber tubing which will not be used in surgical application. Any items where 270°F (132°C) for 5 minutes is appropriate.
POUCHES	270°F (132°C)/ 27 PSI (186 kPa) for 15 Minutes	Instruments in pouches. Loosely wrapped individual instruments. Multiple layers of instruments separated by fabric. Wrapped trays of loose instruments. Rubber tubing. Any items where 270°F (132°C) for 15 minutes is appropriate.
LIQUIDS	250°F (121°C)/ 15 PSI (104 kPa) for 30 Minutes	Liquids or gels that could boil over or spill out of the container. At the end of the sterilizing phase, venting is slowed to allow heat in the liquid to dissipate slowly and eliminate boil overs. There is not a drying phase in the Liquids cycle.
PACKS	250°F (121°C)/ 15 PSI (104 kPa) for 30 Minutes	Common groups of surgical instruments in commercially prepared packs. Surgical instruments subject to prolonged storage. Surgical gloves wrapped for sterilization. Any items other than liquids, where 250°F (121°C) for 30 minutes is appropriate.

*Values are minimums

NOTE

Reprocess instruments to achieve sterility when sterilizing cycle has been terminated prematurely. Failure to do so may result in non-sterile instruments.

Refer to the following pages for detailed program operating procedures.

Detailed Operation

1. Press the “On/Standby” padswitch

   - The Selector/Indicator panel will turn on.
   - The Program indicator lights will flash until a sterilization program is selected.

Do not use this equipment for sterilizing volatile substances or for any purpose other than its intended design. Burns and toxic or explosive conditions could result.

Close and latch the door. The Sterilizer will not operate unless the door is closed.

NOTE

Before operating the sterilizer, be sure the door handle is completely depressed (latched). If the handle is not fully latched, the sterilizer will alert the user with an audible beep and will not start until the door handle is latched.

2. Select a Sterilization Program in accordance with Table 1.

When a sterilization program is selected, the Temperature/Time display will flash the selected program's parameters alternately.

If the wrong program selection is made, a different program may be selected by pressing the correct program padswitch.

WARNING

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in unsterile instruments which could lead to personal injury or death.

EQUIPMENT ALERT

Processing goods using an incorrect sterilization program could result in unsterile goods and may damage instruments. Consult with your supply manufacturer for specific sterilization instructions.

3. Press the “Start” padswitch.

   - The sterilizer will begin processing its load automatically after the “Start” padswitch is pressed.
   - The “Filling” light will illuminate and the chamber will automatically fill to the correct level.
   - The “Sterilizing” light will then illuminate to indicate that the sterilizer has begun the heating and sterilization phase of the selected cycle.

- When the correct temperature and pressure are reached, the sterilizer will begin its time count down. The selected exposure temperature and pressure will be maintained throughout the sterilization phase.
- When the exposure time is complete, the sterilizer will vent the chamber of all steam and water back into the reservoir tank.
- When the venting is complete and the pressure inside the chamber has been reduced to zero, the “Drying” light will illuminate and the sterilizer will begin a 45 minute drying phase if the program selected has a drying phase.
- The load may now be left in the unit to be dried, or it can be removed from the unit if drying is not necessary.

NOTE

The sterility of wrapped or packed instruments cannot be insured unless the wrapped or packed instruments are allowed to dry fully.

- When the 45 minute drying phase has been completed, the sterilizer will signal the operator that the drying phase is complete with five series of three audible “beeps” and the “Complete” light will illuminate indicating that the sterilizer has completed its program cycle.

CAUTION

The processed load and metal inner surfaces will be hot at the completion of the drying phase. Avoid contact.

- The sterilizer load may now be removed from the chamber.

Press the “On/Standby” padswitch.

The Sterilizer may be turned off after the completion of the sterilization program. If additional sterilization program cycles are desired, the sterilizer may be restarted at this time.

Operator Maintenance

DAILY

1. CLEAN EXTERNAL SURFACES

Wipe with a soft dry cloth and wash occasionally with a damp cloth and mild soap or detergent.

WARNING

Prevent the possibility of burns from the sterilizer. Be sure that the unit is cool when cleaning the door gasket and any mating surfaces.

2. CLEAN STERILIZER DOOR GASKET

Clean door gasket and mating surface with a damp cloth. Examine gasket for possible damage that could prevent a good sealing surface.

WEEKLY

1. CLEAN CHAMBER AND TRAYS.

The sterilizing chamber and instrument trays should be cleaned weekly. First, drain the water from the reservoir. A drain tube is located on the front of the unit for draining. Wash the inside of the chamber and the trays with mild soap or Speed-Clean and distilled or demineralized water.

EQUIPMENT ALERT

Do not use abrasive or bleaching agents in the chamber. (i.e. steel wool, scouring powder, bleach, etc.). Never use a wire brush. These materials will damage the metal surfaces of the chamber and components.

Refill the reservoir with distilled or demineralized water.

MONTHLY

1. FLUSH SYSTEM

To protect the intricate parts of the unit, the system must be flushed once a month with Speed Clean Sterilizer Cleaner.

(a) Mix thoroughly four ounces of Speed-Clean with two quarts (approximately 2000 c.c.) of distilled or demineralized water.

(b) Drain reservoir and fill with cleaning solution.

(c) Run one 30 minute cycle (PACKS) at 250°F (121°C). Instruments should not be sterilized while cleaning the sterilizer.

(d) Drain cleaning solution from chamber and reservoir. Fill reservoir with clean distilled or demineralized water and run two 3 minute cycles (UNWRAPPED) at 270°F (132°C).

(e) Drain reservoir and allow sterilizer to cool to room temperature. Remove the trays, tray rack, and the tray plate. This is accomplished by grasping the tray

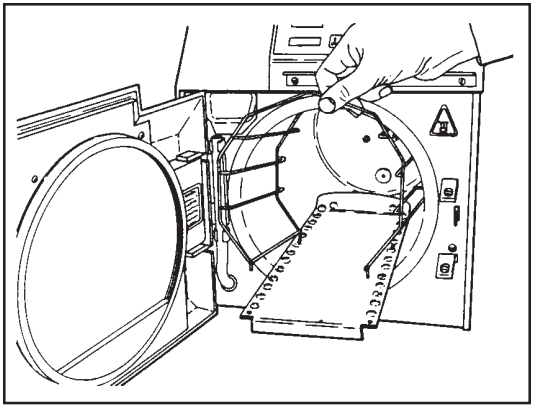


Figure 4

rack on both sides in the front and gently pulling outward. The tray rack and tray plate should slide out of the chamber together. Wipe out the inside of the chamber being careful not to damage the heater element or the temperature and level sensor components. Wipe off the trays, tray rack, and tray plate and replace in the chamber.

When replacing the tray rack and tray plate, raise the front of the tray rack while you are pushing the tray plate into the chamber with the tray rack inserted into back 1/8" holes (See Figure 4).

This will allow the tray rack and tray plate to slide in easier. When the assembly is almost fully in the chamber, insert the tray rack into the front holes of the tray plate and push completely into the chamber.

(f) Refill the reservoir with clean distilled or demineralized water.

(g) Sterilizer is now ready for use.

2. PRESSURE RELIEF VALVE CHECK

The pressure relief valve must be checked each month by a qualified person to be sure that the valve is functioning properly.

The pressure relief valve is located inside the cabinet, on top of the chamber. A rectangular inspection hole is provided on the top cover where, after the inspection cover is removed, the ASME pressure relief valve can be accessed (See Figure 5).

(a) Run a sterilization cycle with no load in the chamber at 270°F (132°C) for 5 minutes.

(b) The pressure relief valve can be tested when the pressure display reaches 27 PSI (186 kPa) minimum. Remove the access cover on the top of the sterilizer. Insert a rod or a screwdriver through the ring on the pressure relief valve (See Figure 5). Pull the valve ring to open for approximately 3 seconds.

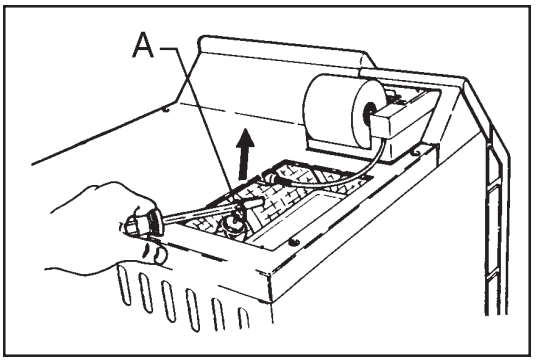


Figure 5: (A) Pressure relief valve

WARNING

Pressure relief valve will be hot. Do not pull ring with bare hands or burns will result. Use a rod or screwdriver. Steam blow-off will be discharged from under the rear of the sterilizer when the ring on the relief valve is pulled. To prevent possible burns to the operator, place a steam barrier (rolled up towel) around the bottom of the sterilizer.

Steam should freely discharge from beneath the rear of the unit.

(c) Release the ring and the steam discharge should terminate completely.

NOTE

If traces of steam continue to escape through the valve, the valve has not reseated properly. Open and close the valve quickly (several times if necessary) by pulling the ring and letting it snap closed.

(d) If the valve malfunctions, the valve must be replaced.

(e) Turn the unit off after the valve check to prevent overheating.

3. CLEANING CHAMBER FILTER

(a) Before attempting this procedure, make sure that the sterilizer has cooled to room temperature.

(b) Open the sterilizer door and remove all trays, tray rack, and tray plate from within sterilizer chamber. Locate the chamber filter on the bottom of the chamber. (See Figure 6).

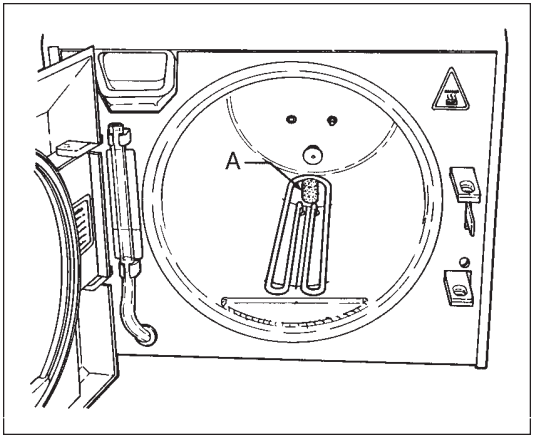


Figure 6: (A) Filter

Grasp the chamber filter and gently pull upwards while twisting slightly. (A pair of pliers may be used if filter is stuck). Filter may be cleaned with mild soap and distilled or demineralized water. A small stiff bristled brush or Ultrasonic Cleaner may be helpful to remove foreign objects from the filter surface. Rinse filter with distilled or demineralized water.

NOTE

If the cleaning methods do not work to effectively clean the filter, replacement may be necessary.

(c) Replace the chamber filter by inserting the filter into the hole in the chamber bottom and pressing downwards while twisting slightly.

EQUIPMENT ALERT

Operating the sterilizer without the filter in place could cause the sterilizer to malfunction.

QUARTERLY

1. REMOVE AND CLEAN DOOR GASKET

Every three months, remove the door gasket and dam gasket from the gasket housing channel and clean the channel per the instructions above.

A small brush, (do not use a wire brush), will aid the procedure. Clean gasket with a mild detergent and inspect the gasket and dam gasket for cracks, cuts, shrinkage, or swelling. Replace the gaskets if necessary.

Press the gasket into the channel and replace dam gasket. Run one sterilizing cycle to seat the gasket.

ANNUALLY

1. REPLACE HEPA FILTER

Every twelve months, have an authorized service company replace the HEPA (high efficiency particulate air) filter located beneath the top cover.

It is the responsibility of the user to establish a periodic maintenance procedure to assure correct operation of the equipment and reliable sterilization of the loads. Contact your Midmark local distributor or representative to develop a program for planned maintenance.

Optional Printer Information

INSTALLING THE PRINTER

WARNING

Disconnect all electrical power to the unit before removing any of the unit's covers / shrouds or making any repairs to prevent the possibility of electrical shock. Failure to comply with these instructions could result in serious personal injury or death.

1. Unplug power cord from wall outlet.
2. Remove top inspection cover (1, Figure 7) from top cover (2).
3. Remove two screws (3) and printer cover plate (4) from top cover (2). Store two screws and printer cover plate in the event that the printer is removed and these parts are needed again.

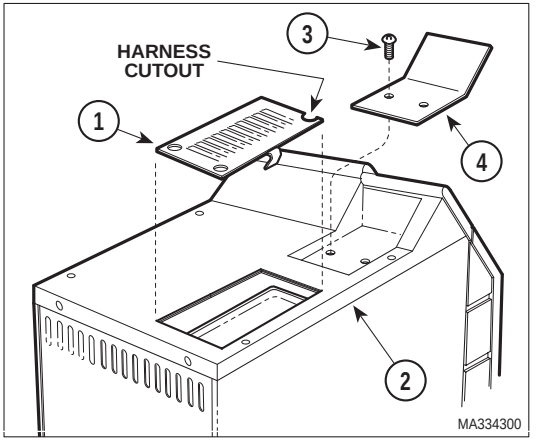


Figure 7: Access Cover Removal

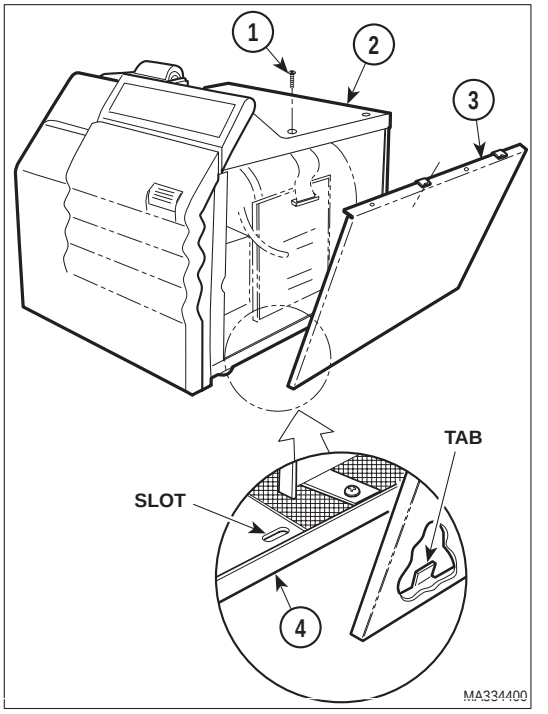


Figure 8: Access To PC Board

4. Remove two screws (1, Figure 8) from top cover (2).

5. Pull outward and down on the top edge of the right hand side panel (3) and remove right hand side panel from sterilizer.
6. Plug PCB printer harness (1, Figure 9) into PC board (2).
7. Route PCB printer harness (1) through harness clip (3) to prevent harness from contacting hot pressure relief valve.
11. Raise top edge of right hand side panel (3) into position and secure using two screws (1).
12. Install top inspection cover (1, Figure 7) on top cover (2), making sure PCB printer harness is routed into harness cutout of top inspection cover.
13. Plug power cord into wall outlet.

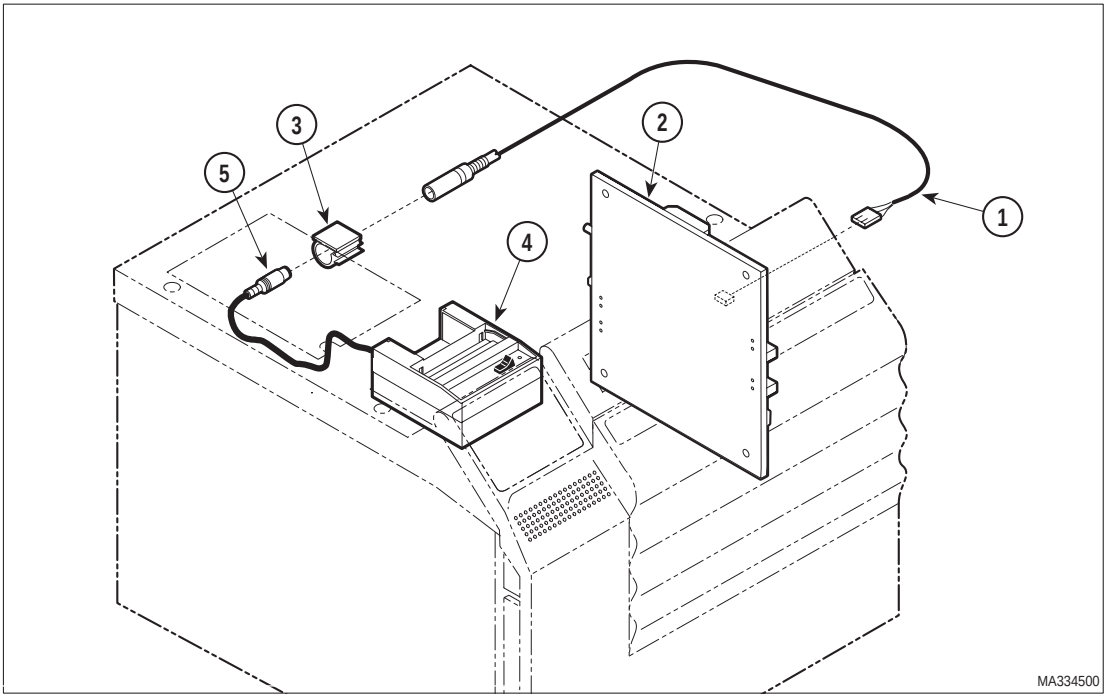


Figure 9: Printer Connections

8. Place the printer (4) on the top cover in the recessed area.
9. Connect PCB printer harness (1) into printer harness (5).
10. Insert two tabs of right hand side panel (3, Figure 8) into two slots of base (4).

OPERATING THE PRINTER

The paper feed switch on the printer is a rocker type switch. Push the left side of the rocker switch to toggle the printer on and off-line. Push the right side of the switch to advance the paper.

INSERTING THE PAPER ROLL

1. Press the left side of the rocker switch to toggle the printer Off. (The light will go off.)
2. Unroll several inches of the paper.
3. Cut a straight edge on the paper roll if it is jagged. This will facilitate the entry of the paper into the printer.
4. Slide the paper into the slot on the back of the printer. You can slide it in about one-quarter inch before it stops. (See Figure 10).
5. Press the left side of the rocker switch to toggle the printer On. (The light will go on.)
6. While holding the paper in place, press the right side of the switch to the “Paper Feed” position and hold.

   The printer will activate and a rubber roller will pull the paper into the printer compartment. Hold the switch in the “Paper Feed” position until the paper emerges from the top of the printer mechanism. When an inch of paper has emerged from the top of the printer, release the switch.
7. Pull the paper through the printer until several inches are exposed.

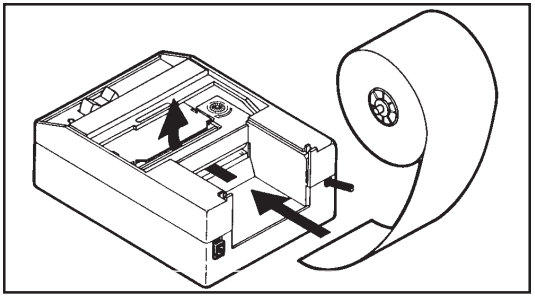


Figure 10

8. Put the paper spindle into the paper roll, and place the roll with the spindle onto the grooves at the back of the printer. Turn the paper roll so as to take-up the slack in the paper feeding to the printer. Make sure the roll of paper turns freely. If it does not turn freely, the paper will jam and possibly damage the printer mechanism.

INSTALLING THE CARTRIDGE RIBBON

The printer takes a cartridge ribbon. When printing becomes faint or difficult to see, you should replace the cartridge. If the printer is used infrequently, the print impression sometimes becomes weak because the ribbon dries out. If the printed material is difficult to read and you suspect this is the cause of the problem, advance to a properly inked portion of the ribbon by pressing and holding the switch in the “Paper Feed” position for 3 seconds.

TO INSTALL THE CARTRIDGE RIBBON:

1. Press the left side of the rocker switch to toggle the printer Off. (The light will go off.)
2. Four small grooves are embossed on the left and right side of the printer cover. With the index finger of each hand, press down gently on these grooves. (See Figure 11).
3. When the printer cover is tilted up to a near-vertical position, you may lift it completely off.
4. Push down on the right side of the ribbon cartridge (marked “Push”) and remove the old cartridge ribbon. (See Figure 12).
5. Install the new cartridge ribbon. Be sure the ribbon is inserted in front of the paper and the ribbon is flat against the paper. Press the cartridge ribbon downward until it snaps into place.

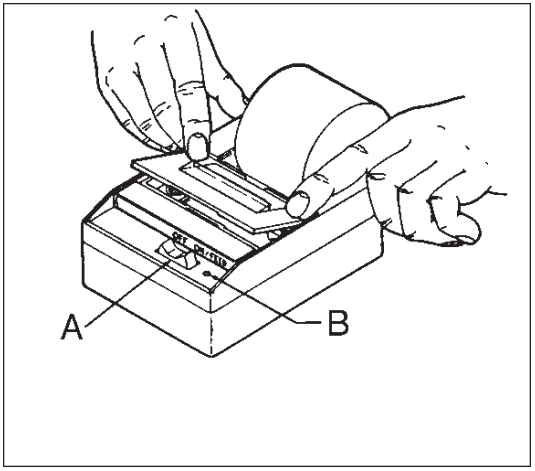


Figure 11: (A) On/Off paper feed switch; (B) Indicator light

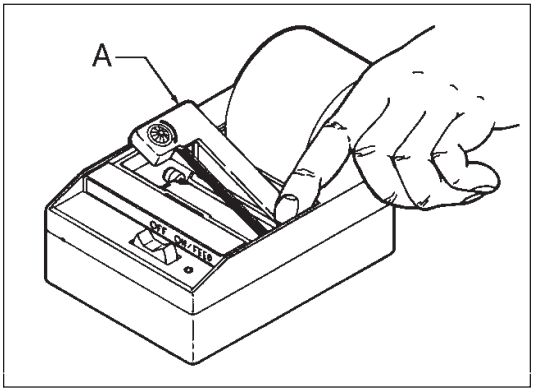


Figure 12: (A) Ribbon Cartridge

NOTE

If you get ribbon ink on the printer plastic case, wipe it off immediately. Once it dries, it is difficult to remove.

6. Turn the “knob” on the cartridge ribbon (marked by an arrow) clockwise to stretch the ribbon so it is tight.
7. Replace the printer cover.

REMOVING THE PAPER ROLL:

Before removing the paper roll, advance the paper about one inch beyond the paper cutter by pressing down and holding the switch to the “Paper Feed” position. Lift the paper roll away from the printer housing and with a scissor, cut the paper roll feeding to the printer. Try to make the cut as straight as possible to facilitate the next reloading of the paper. You may now pull the remaining paper through the printer mechanism.

EQUPMENT ALERT

Be sure to pull the paper out of the top of the printer (paper cutter side). Pulling the paper out of the back of the printer will damage the print mechanism.

POWER UP MESSAGE:

When the printer is first turned on, it prints the word “Ready” to assure you that its built in microprocessor is working properly.

When turning the printer Off, wait at least 3 seconds before turning the printer back on.

PRINTER TAPE DESCRIPTION

The printer will print the following information for each program cycle:

Set Temperature

Set Time

Run Number

Date: a blank line is printed so that the date can be recorded on the printer tape. (See Figure 13).

During the "heat up phase" of the program cycle, the printer will print the chamber temperature, the chamber pressure, and the time elapsed in two (2) minute increments.

During the actual “Sterilization Phase” of the program cycle, the printer will record the chamber temperature, the chamber pressure, and the time elapsed in 30 second increments.

When the sterilizer has completed the “Sterilization Phase” of the program cycle, the printer will print the "Minimum Temperature", "Maximum Temperature", "Minimum Pressure", and "Maximum Pressure". Next, the word "Vent" will be printed to show that the steam pressure was exhausted from the chamber. During the actual "drying phase" of the program cycle, the word "Drying" will be printed followed by the time elapsed during the drying phase in five (5) minute increments. At the end of the drying phase, the printer will print the total process time for the entire cycle.

Finally, the word “Complete" will be printed to show that the sterilizer has completed the sterilization program cycle. Figure 13 shows an example of a typical printout of a program cycle.

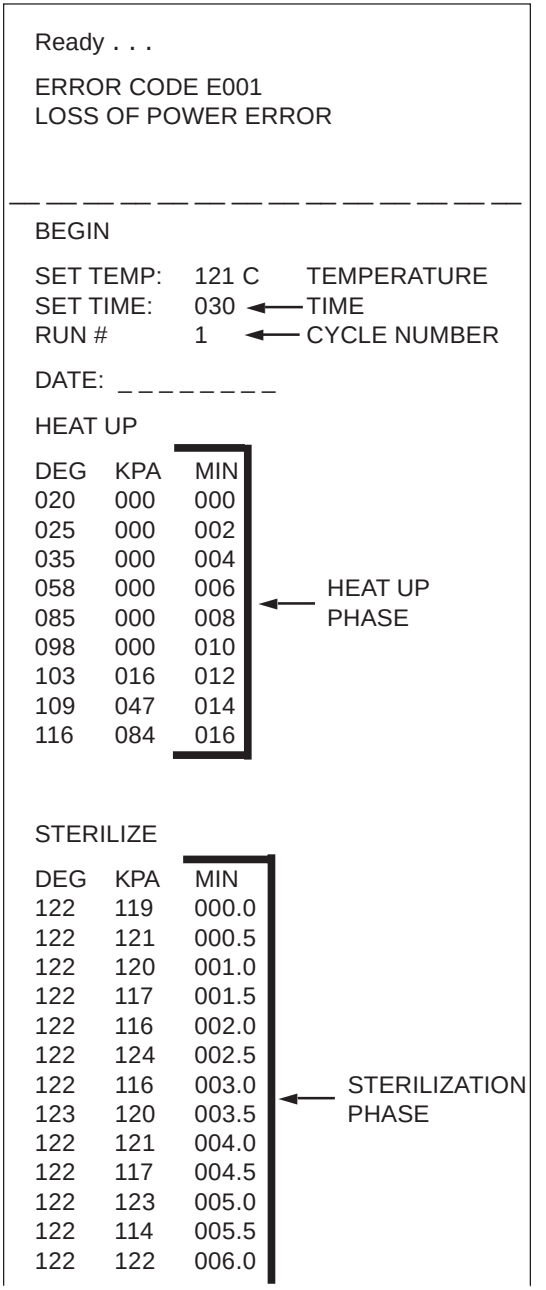


Figure 13

Continued on next page

122	114	006.5
123	119	007.0
122	114	007.5
123	119	008.0
122	115	008.5
123	116	009.0
122	115	009.5
123	115	010.0
122	115	010.5
122	113	011.0
122	116	011.5
123	114	012.0
122	115	012.5
123	113	013.0
122	114	013.5
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122	109	017.0
122	114	017.5
123	111	018.0
122	108	018.5
122	109	019.0
122	111	019.5
123	109	020.0
122	109	020.5
122	108	021.0
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122	105	024.0
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122	104	025.0
122	109	025.5
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122	107	026.5
122	105	027.0
122	106	027.5
122	105	028.0
123	106	028.5
122	104	029.0
122	105	029.5
122	108	030.0

MIN TEMP 122
MAX TEMP 123
MIN PRES 104
MAX PRES 124

VENT

DRYING

MIN

000
005
010
015
020 ← DRYING PHASE
025
030
035
040
045

78:81
TOTAL PROCESS TIME
COMPLETE

Figure 13 - Continued

Table 2. Trouble-Shooting Guide

Trouble	Possible Cause	Remedy
A. Water Low Light Is On.	Not enough water in reservoir tank to fill chamber.	Add distilled or demineralized water to reservoir tank.
B. Door Ajar Light Is On.	Chamber door not fully closed.	Shut door properly.
C. Error Light Is On.		See Error Code Guide (Table 3) for detailed explanations of error codes.
D. Steam Is Escaping From Pressure Relief Valve.	Valve was not properly reseated after pressure relief valve inspection.	Follow instructions in this manual for the Pressure Relief Valve Check.
E. No Color Change On The Chemical Indicator Strip (or incomplete change)	1. Satisfactory sterilization has not taken place. 2. The chemical indicator has come into contact with water in the sterilizer. 3. The chemical indicator has been stored in a damp and/or hot condition.	Repeat cycle with a fresh chemical indicator. If problem occurs again, unplug unit and contact an authorized service representative.
F. Positive Biological Indicator.	1. Insufficient steam penetration. 2. Insufficient air removal. 3. Insufficient temperature or pressure. 4. Wrong type of biological indicator for this sterilizer or wrong cycle used for biological indicator.	1. Reduce load weight or check if load is packed too tightly. 2,3. Contact an authorized service representative. 4. Check biological indicator instructions to make sure indicator is for a gravity type sterilizer, check for proper cycle times and temperatures. Contact biological indicator representative.
G. Door Gasket Leaks	1. Gasket damaged or dirty. 2. Sterilizer not level.	1. Allow sterilizer to cool, then clean or replace door gasket by following the instructions in this manual. 2. Level sterilizer.
H. Packs Not Dry.	1. Sterilizer overloaded. 2. Chamber filter clogged. 3. Sterilizer not level. 4. Input voltage too low. 5. HEPA filter clogged.	1. Reduce load weight or check if load is packed too tightly. 2. Allow sterilizer to cool, then clean or replace filter following instructions in this manual. 3. Level sterilizer. 4. Connect sterilizer to a separate (dedicated) circuit. 5. Replace HEPA filter.

Table 3. Error Code Guide

Error Code and Explanation	Possible Cause	Remedy
Error Code 1: Power Interruption To Sterilizer.	1. Unit powered up for first time. 2. Power was interrupted by power outage. 3. Overheat switch activated.	1. Press On/Standby. Continue normal operation. 2. Press On/Standby. Continue normal operation. 3. Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 2: Stop Button Pushed During Cycle.		Restart sterilizer after unit stops beeping.
Error Code 3: On/Standby Button Pushed During Cycle.		Restart sterilizer after unit stops beeping.
Error Code 4: Door Ajar During Cycle.	1. Door opened during cycle. 2. Door Switch not functioning properly.	1. Restart sterilizer after unit quits beeping. 2. Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 5: Excessive Pressure.	1. Sterilizer Overloaded with gauze or linen packs. 2. Unit out of calibration or air valve defective.	1. Reduce the load in the sterilizer. Restart unit. 2. Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 6: Excessive Temperature.	1. Unit out of calibration.	1. Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 7: Pressure Low During Cycle.	1. Leaking door gasket. 2. Internal leak in unit plumbing.	1. Allow sterilizer to cool, then clean or replace door gasket by following instructions in this manual . 2. Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 10, 11, 12: Hardware/Software Error		Allow sterilizer to cool completely. Restart sterilizer. If unit errors again, unplug unit and contact an authorized service representative.
Error Code 15: Stop Button or ON/ STANDBY Button Pushed During Drying Cycle.		Restart sterilizer after unit stops beeping.

Limited Warranty

LIMITED WARRANTY

SCOPE OF WARRANTY
Midmark Corporation ("Midmark") warrants to the original purchaser its new Alternate Care products and components (except for components not warranted under "Exclusions") manufactured by Midmark to be free from defects in material and workmanship under normal use and service. Midmark's obligation under this warranty is limited to the repair or replacement, at Midmark's option, of the parts or the products the defects of which are reported to Midmark within the applicable warranty period and which, upon examination by Midmark, prove to be defective.

APPLICABLE WARRANTY PERIOD
The applicable warranty period, measured from the date of delivery to the original user, shall be one (1) year for all warranted products and components.

EXCLUSIONS
This warranty does not cover and Midmark shall not be liable for the following: (1) repairs and replacements because of misuse, abuse, negligence, alteration, accident, freight damage, or tampering; (2) products which are not installed, used, and properly cleaned as required in the Midmark "Installation" and or "Installation / Operation Manual for this applicable product. (3) products considered to be of a consumable nature; (4) accessories or parts not manufactured by Midmark; (5) charges by anyone for adjustments, repairs, replacement parts, installation, or other work performed upon or in connection with such products which is not expressly authorized in writing in advance by Midmark.

EXCLUSIVE REMEDY
Midmark's only obligation under this warranty is the repair or replacement of defective parts. Midmark shall not be liable for any direct, special, indirect, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

NO AUTHORIZATION
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003-0857-00 Rev. D (10/99)